University Hospitals Bristol NHS
NHS Foundation Trust

Research Guidance Sheet No. 7[a]
Approval - IMP Studies

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Principal Investigators whose studies have recently been approved by the Trust may find the following information helpful in setting out some of their responsibilities for the conduct of their research.

ICH-GCP booklet

If you do not already have a copy of this publication the Research Management Office will be pleased to send you one. This booklet is a consolidated document detailing the ICH Harmonised Tripartite Guideline for Good Clinical Practice in the conduct of clinical trials. It provides details of Investigator's responsibilities, covers aspects of preparation, monitoring, reporting and archiving, and lists essential documents required for the conduct of a clinical trial which must be retained for 15 years following completion of a clinical trial.

Investigator Site File (ISF) template

All trials must have a site file or equivalent to promote successful management of research and aid in document storage. To facilitate this, the Research Management Office has produced a template for an Investigator Site File (ISF). The template contains a list of all essential documents required to be stored at site in order that your study be conducted in accordance with ICH-GCP and applicable regulatory requirements. The site file template can be downloaded from the research website. In addition the site file front page includes a template for a file sticker. We recommended that this outline is used to produce a sheet of file stickers. These stickers should then be used to identify patient files and patient medical notes with your study. The ISF template is only a guide to how studies may be managed and the Research Management Office supports the use of similar files.

Monitoring

Under ICH-GCP and the Department of Health's Research Governance Framework, UH Bristol has a responsibility to monitor research studies conducted on its premises. In addition to this, the Medicines for Human Use (Clinical Trials) Regulations 2004 bring with them a number of obligations the Trust must fulfil. As a result the Research Management Office has developed procedures and methods to meet the requirements. The purpose of monitoring will be to support and assist research active staff in conducting studies in compliance with ICH-GCP and the appropriate regulatory requirements. Should your study be identified for monitoring you will receive a letter to inform you of our intent to monitor and we will contact you to arrange a date for a monitoring visit. You may also request that your study be monitored by the Research Management Office, more information about our monitoring process can be found on the guidance sheet 'Monitoring of Research Studies'.

Reports required

The Chief Investigator (CI) must supply the Research Ethics Committee (REC) with an annual progress report each year of the study's duration and inform the main REC when the study ends; more information on this can be found on the NRES website. The Research Management Office must also be supplied with a copy of the report made to the REC and the Principal Investigator (PI) must inform the Research Management Office of the completion of the study. The Research Management Office will check the details it holds on each study annually by sending the PI a verification form for completion. The CI also has the responsibility to provide the MHRA with an annual safety report; more information on this is contained in the guidance sheet 'Responsibilities of the holder of a CTA'.

Amendments

Substantial amendments made to any study specific documentation must also be reported to the main REC, the MHRA and the Research Management Office and further information regarding amendments can be found on the guidance sheet Amendments to Study Specific Documentation.

Safety

The PI should ensure that all members of the research team are familiar with the UH Bristol Research Related Adverse Event Reporting Policy. This document details your responsibilities as an investigator in reporting SAEs and SUSARs. The Policy and reporting forms are available on the research website. Where other sponsoring organisations have provided similar forms these may be used instead of UH Bristol forms.